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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/050,366 03/31/98 JOHANSSON

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EXAMINER

MOEZIE.F

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/050,366

Applicant(s)
Jfohannsson et al

Examiner
F. MOEZIE

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-24 and 41 is/are pending in the application.
- 4a) Of the above, claim(s) 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 21 20) ☐ Other:

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DETAILED ACTION

STATUS OF CLAIMS

Claims 22-24 are pending prosecution in this Office action.

This application is a CPA, filed 5/4/00, paper no. 18. Along with the request for filing a CPA, applicant submitted a Preliminary Amendment wherein claims 19-24 and 27-30 were canceled. Therefore, claim 28 is not available for action. Currently, claims 22 (trice amended)-24 and 41 are pending in this application. The earlier inadvertent inclusion of claim 28 in the list of claims is regretted.

Newly submitted claim 41(added Oct. 20, 2000) directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original claims are drawn to **a method for treating a patient for insulin resistance** having Metabolic Syndrome, whereas the newly added claim 41 is drawn to **a method for increasing insulin sensitivity, non-elected subject matter**, of a patient having the Metabolic Syndrome.

Since applicant has received an action on the merits for the originally presented invention (a method of treating a patient for insulin resistance), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 41 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Cancellation of claim 41 is suggested.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

INFORMATION DISCLOSURE STATEMENT

The information Disclosure Statement filed 20 October 2000, paper no. 21, has been considered and made of record.

SPECIFICATION - OBJECTION

The specification remains objected to regarding inaccuracies and/or inconsistencies, for example, compare the terms "Metabolic syndrome" at page 1, line 3 with "Metabolic Syndrome" at page 1, lines 13 and 22. A review and correction of the specification is suggested.

Claims 22-24 are rejected as being based on a specification which has been objected to. See also claim 22 for "syndrome".

REJECTION - 35 U.S.C. 102 (b)/103 ©

Claims 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Johansson et al in Metabolism, Vol 44, No. 9, pages 1126-1129, September 1995 (Form PTO-1449 ak).**

Johansson teaches that "Growth Hormone-Deficient Adults Are Insulin-Resistant" Abstract including the Title. This reference further teaches that the use of rhGH "after 6 months

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of rhGH treatment, insulin sensitivity was restored to baseline values. It is likely that the favorable changes in body composition, such as an increase in lean body mass and a decrease in abdominal and visceral adipose tissue, induced by rhGH treatment the insulin antagonistic effect of GH", page 1129. See, the entire document.

An ordinary art skilled at the time the invention was made would have immediately envisaged the use of GH for treating insulin resistance in a patient having the (Metabolic Syndrome comprising) abdominal/visceral obesity in view of the teachings of the art - absent evidence to the contrary.

RESPONSE TO REMARKS

Applicant's responses filed 10/20/00 and 4/10/01, papers no. 22 and 24, respectively, have been considered and found persuasive.

The earlier rejection of the claims under 35 U.S.C. 112, first and second paragraphs, is withdrawn in view of the amendment and remarks.

The rejection of the claims under 35 U.S.C. 102 (b)/103 (a) over Sonksen is withdrawn in view of the applicants' remarks.

CONCLUSION

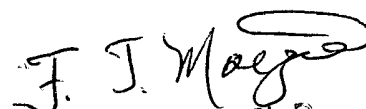
No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. Low (SPE) at 308-2923.


F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
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